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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/840,755

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EXAMINER

CHOI, PETER Y

ART UNIT

PAPER NUMBER

1771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/27/2006

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/840,755

Applicant(s)

TOPOLKARAEV ET AL.

Examiner

Peter Y. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6,8-14 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6,8-14 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**FINAL ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2-6, 8-14 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the amended claims, the limitation “monolayer” does not appear to be in the disclosure as originally filed. The disclosure does not indicate or suggest the limitation that the biodegradable film comprises a biodegradable monolayer film. As such, the limitation may not be added to the claims as the limitation was absent from the disclosure as originally filed.

For purposes of this examination, Examiner defines “monolayer” or more accurately a “monolayer film” as a film layer with uniform boundaries wherein the components of the film are present in the same layer.

3. Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The new claims refer to a personal care product wherein the biodegradable monolayer was stretched while in contact with an aqueous solution (claim 24) and to a personal care product comprising a stretched biodegradable film (claim 25). The limitations referring to “stretching” the biodegradable film are not in the disclosure as originally filed. The disclosure only appears to suggest stretching the precursor film, which is

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used to produce the biodegradable film, but not the biodegradable film itself (paragraph 0057).

As such, the limitations may not be added to the claims as the limitations were absent from the disclosure as originally filed.

#### *Claim Objections*

4. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

#### *Claim Rejections - 35 USC § 102/103*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 2-6, 8-14 and 17-25 are rejected under 35 U.S.C. 102(e) or 103(a) as being anticipated by USPN 6,514,602 to Zhao.
7. Claims 2-6, 8-14 and 17-21 remain rejected as substantially set forth in the Non-Final Rejection of August 14, 2006, sections 3 and 4.

Regarding claim 22, the biodegradable film is a stretched film wherein the biodegradable polymer and the water-soluble polymer comprise a blended mixture (column 3 lines 20-35, column 2 lines 60-67). It should be noted that the biodegradable thermoplastic polymer and water-soluble thermoplastic polymer are present in the same layer so the Examiner submits that "blended mixture" is present as claimed by Applicant.

Regarding claim 23, the water-soluble polymer is polyethylene oxide, polyethylene glycol, or a copolymer thereof (column 4 lines 55-69).

Regarding claim 24, the biodegradable film in Zhao may be stretched (column 3 lines 20-35). Although the Zhao reference does not appear to teach that the biodegradable film was stretched while in contact with an aqueous solution, the prior art structure is identical to the claimed structure. Therefore, the Zhao reference is deemed to anticipate the claimed limitation that the biodegradable film was stretched while in contact with an aqueous solution.

Regarding claim 25, the biodegradable film is stretched wherein the biodegradable monolayer film comprises a blended mixture comprising a biodegradable polymer and a water soluble polymer, wherein the water soluble polymer is polyethylene oxide, polyethylene glycol, or a copolymer thereof, and wherein the film was stretched while in contact with an aqueous solution such that the biodegradable film has a water vapor transmission rate of greater than about 2500 g/m<sup>2</sup>/24 hrs. (see entire document including column 3 lines 20-35, column 2 lines 60-

67, column 4 lines 55-69, column 7 lines 35-45). It should be noted that the biodegradable thermoplastic polymer and water-soluble thermoplastic polymer are present in the same layer so the Examiner submits that “blended mixture” is present as claimed by Applicant.

In the event it is shown that Zhao does not disclose the claimed invention with sufficient specificity, the invention is obvious because Zhao discloses the claimed constituents and discloses that they may be used in combination.

### *Response to Arguments*

8. Applicants’ arguments filed October 2, 2006 have been fully considered but they are not persuasive. First, Applicants argue that the Zhao reference “does not disclose or suggest a monolayer film in accordance with” the limitations set forth in claim 21 (Applicants’ remarks, page 6). Second, Applicants argue that the Zhao reference “does not disclose or suggest a film comprising from about 70% to about 95% biodegradable polymer by weight of the biodegradable monolayer film” (Applicants’ remarks, page 6). Third, Applicants argue that the Zhao reference “fails to disclose a film necessary [sic] having a water vapor transmission rate (WVTR) of greater than about 2500 g/m<sup>2</sup>/24 hrs” (Applicants’ remarks, page 7). Lastly, Applicants argue that new dependent claim 24 and new independent claim 25 containing the additional limitation of stretching the film while in contact with water is neither taught nor suggested by the prior art of record (Applicants’ remarks, page 7).

9. Regarding Applicants’ argument that the Zhao reference does not disclose or suggest a monolayer film in accordance with the limitation set forth in claim 21, Examiner respectfully disagrees. Essentially, Applicants argue that the Zhao reference discloses a multilayer film

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whereas the claimed reference is a monolayer film. It should be noted that the specification does not define “monolayer” in any manner and Examiner defines “monolayer film” as a film layer with uniform boundaries wherein the components of the film are present in the same layer. As set forth in the Non-Final Rejection of August 14, 2006, the Zhao reference teaches a biodegradable layer comprising a biodegradable thermoplastic polymer and a water-soluble thermoplastic polymer are present in the same layer (column 2 lines 60-67, column 8 lines 32-36). Since the Zhao reference teaches a monolayer film, which is not contrary to Applicants’ disclosure or claimed invention, the Zhao reference is deemed to anticipate the claimed monolayer film.

10. Regarding Applicants’ argument that the Zhao reference does not disclose or suggest a film comprising from about 70% to about 95% biodegradable polymer by weight of the biodegradable monolayer film, Examiner respectfully disagrees. The biodegradable polymer comprises 65-100% and the water-soluble polymer comprises 0-35% of the biodegradable layer, which is analogous to the biodegradable monolayer film (column 2 lines 60-67). Therefore, as the biodegradable polymer and the water-soluble polymer overlap the claimed ranges, the Zhao reference is deemed to anticipate the claims.

Applicants misconstrue Examiner’s interpretation of the claimed invention. Applicants submit that if “one were to calculate the maximum amount of biodegradable polymer in a film embraced by Zhao’s disclosure, that film would have no more than 58% biodegradable polymer” (Applicants’ remarks, pages 6 and 7). Applicants arrive at this calculation based on a two-layer film (Applicants’ remarks, page 7 footnote).

It should be noted that claim 21 claims "a personal care product comprising a biodegradable monolayer film." The claim is anticipated by the prior art, even if the prior art discloses multiple layers so long as a layer is a biodegradable monolayer film comprising the limitations and properties set forth in claim 21. The biodegradable polymer and water-soluble polymer comprising the monolayer film are present in the same layer and comprise percentages of 65-100% and 0-35% respectively. The second layer that Applicants' apply as a basis for the calculation is irrelevant to the percentages of the biodegradable polymer and water-soluble polymer used in the rejection. Therefore, the Zhao reference is deemed to anticipate the claims.

11. Regarding Applicants' argument that the Zhao reference fails to disclose a film necessary having a water vapor transmission rate (WVTR) of greater than about  $2500 \text{ g/m}^2/24 \text{ hrs.}$ ,

Examiner respectfully disagrees. Zhao discloses a film having a WVTR of at least about  $1000 \text{ g/m}^2/24 \text{ hrs.}$ , which reads on the claimed range of greater than about  $2500 \text{ g/m}^2/24 \text{ hrs.}$

Applicants contend that the Zhao reference "does not provide any reasonable expectation that the disclosed films would necessarily achieve a WVTR of greater than about  $2500 \text{ g/m}^2/24 \text{ hrs.}$ ," yet Applicants also agree that Zhao discloses a range which encompasses the claimed range. Since the claimed range is not specific, absent unexpected results in the claimed range of about  $2500 \text{ g/m}^2/24 \text{ hrs.}$  and a limitless WVTR, the Zhao reference anticipates the claimed range.

12. Regarding Applicants' argument that the additional limitation of stretching the film while in contact with water, as set forth in new claims 24 and 25, is neither taught nor suggested by the prior art of record, the Examiner respectfully disagrees. Applicants contend that "the claimed films will have a materially different structural configuration as compared to stretched films



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described in the prior art of record” (Applicants’ remarks, page 7), yet Applicants fail to explain the differences between the claimed film and the film in the prior art.

Applicants contend that “stretching a film comprising a blended mixture containing water-soluble polymer while in contact with water will produce microvoids in precursor film areas previously containing water-soluble polymer” (Applicants’ remarks, page 7). Essentially, Applicants contend that stretching produces microvoids in precursor films. The specification discloses that the precursor films are subsequently “processed to produce a biodegradable film that has the desired characteristics of porosity, breathability, and ductility” (paragraph 0057). The claimed invention, though, is not the precursor film, but the biodegradable film which is produced from the precursor film. Even though properties may exist in the precursor film, those properties may not exist in the claimed invention. Since the structure in the Zhao reference is identical to the claimed structure and possesses identical properties to the claimed invention, the Zhao reference is deemed to anticipate claims 24 and 25.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

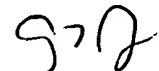
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Y. Choi whose telephone number is (571) 272-6730. The examiner can normally be reached on Monday - Friday, 08:00 - 15:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Peter Y. Choi  
December 19, 2006



ANDREW PIZIALI  
PRIMARY EXAMINER